REMARKS

Upon careful and complete consideration of the Office Action dated March 26, 2002, applicants have amended the claims which, when considered in conjunction with the comments hereinbelow, are deemed to place the present application into condition for allowance. Favorable reconsideration of this application, as amended, is respectfully solicited.

In the Office Action, claims 31-34 were rejected under 35 U.S.C. §101 for being directed to non-statutory subject matter. These claims have been cancelled and re-written as new claims 52-56. Accordingly, the rejection of claims 31-34 is now moot.

The Office Action went on to reject claims 2, 3, 7, 8, 10-14, 16, 19, 24, 27 and 28 under 35 U.S.C. §112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In response to these allegations, the majority of these claims have been amended, as well as additional claims being filed to cover the various limitations. Claims 12-14 were rejected, but no amendments were made to these claims, as it is believed that these claims are in acceptable form. It is further noted that claim 26 was not rejected, but did fall under the general rejection and has thus been amended as well.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

The Office Action then rejected claims 23-30 and 35-39 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,105,801 to Dogliotti (hereinafter referred to as "Dogliotti"), U.S. Patent No. 5,162,517 to Darsow (hereinafter referred to as "Darsow") and U.S. Patent No. 5,139,795 to DuRoss (hereinafter referred to as "DuRoss"). The Office Action has

alleged that these references teach crystalline xylitol and products containing the same as is claimed. Applicants respectfully disagree with this rejection.

Before addressing the teachings of the cited references, it is believed worthwhile and beneficial to review the novel process for the crystallization of xylitol disclosed by the present invention and the novel products obtained thereby. In order to do this properly, the process of the present invention will be reviewed in detail.

The process of the present invention comprises a suspension crystallization wherein a solution of xylitol is sprayed as minute droplets into warm air. The air also contains suspended fine solid microcrystalline xylitol particles. The solvent (water) of the solution immediately starts to evaporate and some of the minute droplets start to crystallize into minute solid particles, microcrystals. Other ones of the droplets come into contact with the surface of the solid microcrystalline xylitol particles suspended in the warm air.

When the suspended liquid or crystallizing xylitol droplets contact the solid xylitol, the droplets adhere to the surface of the solid xylitol particles and start to crystallize there. At the same time the particles and droplets are in a constant motion and repeatedly crock into each other. Sometimes two or more particles or crystallizing droplets may adhere together in a totally random manner forming larger entities. These entities may yet again become adhered to other randomly adhered particles until a porous agglomerated structure of minute crystallized and crystallizing particles is formed.

It is evident that when such discrete minute crystals adhere together because their surface is sticky (wetted with a layer of liquid xylitol) it is only a local surface contact which is provided between the particles. The remaining surfaces and the inner portions between the minute crystals (the microcrystals) are still clearly discernible at least with a microscope. Between discrete

microcrystals there is more or less empty space. Thus, a porous particulate microcrystalline structure is created. These porous and partly still sticky structures are gathered together on a surface to form a loose porous agglomerated structure or bed.

In the process according to the present invention, the suspension crystallization is followed by a conditioning and drying step which is performed in such a manner as to allow the crystallization of the xylitol in the discrete adhered particles to proceed fully so that the resulting cluster of crystalline material is composed essentially of minute separate crystalline particles agglomerated together. The agglomerate is then broken up to form a particulate crystalline product wherein each particle is composed of a multitude of adhered minute microcrystals.

The suspension crystallization of the present invention provides a crystalline agglomerated structure of discrete microcrystals adhered more or less rigidly to each other. Such a product differs entirely from the prior art xylitol crystals.

The product as such is particulate since it is formed of discrete particles. Each particle has been formed either by direct crystallization or by the breaking up of a larger agglomerate of microcrystals. The microcrystals in turn have been formed by the contacting and adhering to each other of sticky minute xylitol particles which have just crystallized or are on the verge of crystallizing. The sticking together of such particles has formed bigger entities. Because the contacting has taken place in a suspended state, the particles have met totally at random and have also adhered together to form random agglomerates.

The solid material fed into contact with the droplets of crystallizing xylitol liquid is also microcrystalline, i.e. is made of clusters of microcrystals originating from a microcrystallization process. Thus, the resulting entire structure will be made up of a myriad of microcrystals adhered together.

The suspension crystallization of the present invention thus results in a novel product, which has novel characteristics. Because of the suspension crystallization process, the product is homogeneous and porous. It is a solid crystalline material but it is much more easily broken into smaller particles and the mechanical grinding force required is low.

The microcrystalline structure of the particles is very important since it gives the product very specific characteristics. Thus, it has been shown that the compressibility of the particles is exceptionally good probably due to the fact that the comparatively loosely bound microcrystals in the porous structure can fairly easily be pushed in relation to each other. Thus, they can be compacted more easily than a conventional crystalline product wherein compacting includes the breaking of bigger crystals.

As reviewed above, it is quite clear that the process of the present invention produces a suspension-crystallized product which has very specific and unique physical characteristics. Returning to the Office Action, the rejection of the claims and the cited references, applicants respectfully submit that the Office Action has failed to realize that the present invention claims a very special form of crystalline xylitol, a form that is not taught, disclosed nor suggested by the prior art references.

More specifically, the present invention relates to a particulate crystalline xylitol product which is such that each particle throughout its entire structure consists of microcrystals of xylitol. Furthermore, the microcrystals are of a very special kind in that they are formed by suspension crystallization in a gas and the microcrystals are agglomerated together in a random manner to form the microcrystalline xylitol product. The suspension crystallization which is part of the product definition provides a distinct porous and compressible character to the crystalline xylitol

product. It is this crystalline xylitol product of the present invention that is claimed and believed to be distinct from the crystalline xylitol products of the prior art.

Dogliotti is directed to a process for providing a xylitol coating on dragees with what is referred to in Dogliotti as "microcrystalline xylitol". More specifically, the dragees are coated with a xylitol shell. This shell on the dragees is formed by an intimate mixture of microcrystals of xylitol with a solid fatty substance. According to Dogliotti, the purpose of the shell on dragees is to preserve the cores and provide a mechanical barrier on the cores. A good shell is compact, smooth and abrasion or shock resistant.

Dogliotti discloses that xylitol can be used as a shell material provided that it is mixed with a fatty substance which provides the desired compactness and smooth aspect to the shell. The fatty substance included in the xylitol of Dogliotti provides the xylitol with a compact character which is in sharp contrast to the porous and compressible character which is a feature of the crystalline xylitol product of the present invention wherein each particle substantially throughout its entire structure consists of a multitude of suspension crystallized microcrystals of xylitol agglomerated together in a random manner.

The xylitol of Dogliotti is provided as a compact shell on the outer surface of dragees and it is consequently very clear that it is not a particulate product which throughout its entire structure consists of microcrystalline xylitol such as defined in the product claims of the present application. It is further evident that the xylitol of Dogliotti could not be used as a free flowing sweetener or for compression into tablets, both of which are typical features of the product in accordance with the present invention.

Darsow is directed to the production of xylitol by hydrogenation and only marginally touches on the issue of crystallization. Although Darsow discusses crystalline xylitol and its

uses as a sweetener in various end uses which are partly similar to those of the present invention, there is no indication, i.e. teaching nor suggestion, that the xylitol product of Darsow is a microcrystalline xylitol product. If anything, it is quite the contrary. It is further emphasized that the use of Darsow's xylitol does not anticipate the use of the distinct microcrystalline xylitol product of the present invention.

In Example 1 of Darsow, there is a description of its production of crystalline xylitol by crystallization in a vacuum crystallizer with cooling. Such a cooling crystallization is an aqueous crystallization which provides normal xylitol crystals which are 100 to 1000 times larger than the microcrystals of the present invention. Each particle of Darsow consists of one single crystal and there is no random agglomeration of these crystals as claimed in the present invention. Such crystals of Darsow have the well known sweet taste of xylitol but they do not have the physical properties which are characteristic of the present microcrystalline xylitol product.

DuRoss teaches melt crystallized xylitol as distinguished from the standard aqueous crystallized xylitol. Such aqueous crystallization has already been discussed above in connection with Darsow. The present invention relates to a crystalline xylitol product which is distinct from both of the above types, i.e. to a suspension crystallized xylitol, wherein microcrystals of xylitol have been formed in gas and the suspended microcrystals have been agglomerated in a random manner by colliding with each other in a gas suspended state.

The microcrystals of DuRoss have been formed by the agitation of a viscous molten mass of xylitol containing only a very small proportion (less than 2%) of water. Cooling of the molten mass has provided solidification. The continuous agitation has prevented the molten mass from setting into one large solid and has provided instead a microcrystalline structure. It is, however,

clear to those skilled in the art that the agitation of a viscous molten mass cannot provide the same kind of microcrystalline character as the suspension crystallization of the present invention, where the discreet microcrystals are formed in the suspended state in a gas and then combine into agglomerates by colliding in the gas and adhering to each other to provide larger entities.

More specifically, the crystallization of DuRoss is a melt crystallization wherein a xylitol solution is cooked at a high temperature to provide a melt containing less than 2% moisture. The hot mixture is continuously stirred with an agitator. Just before crystallization, seed crystals of finely ground xylitol are added to the vortex of the viscous mixture and the stirring is continued at high speed. Crystallization takes place in the viscous melt. The melt mass is poured on a tray where it finally crystallizes into a white solid.

In contrast to the above, the present process comprises a suspension crystallization, wherein the xylitol crystallizes well below its melting temperature from an aqueous solution. This provides a very homogeneous crystalline product. Each crystal is separately formed in the air and adheres to the next crystal also in the air. The crystals grow gradually into bigger, loosely tied agglomerates.

In the melt crystallization of DuRoss, the xylitol melt forms a continuous mass, wherein the crystals crystallize within the mass, in contact with the mass and totally surrounded by the mass. The agitation breaks up crystal bridges formed in the mass and prevents the formation of one huge compact crystal cake. However, it is evident that the discrete crystal nature of the product which is obtained in the suspension crystallization of the present invention cannot be obtained by the melt crystallization taught by DuRoss.

Due to the discrete crystal agglomeration, the suspension crystallized xylitol of the present invention will easily break into discrete small particles which provide a freely flowing

product which is very useful in industrial processes. Moreover, it should be also noted that the melt crystallization of DuRoss starts from seed crystals which are not microcrystalline in themselves. Accordingly, at least some of the microcrystals of DuRoss will have cores which are not microcrystalline in nature. This is in contrast to the present invention which requires that the product should be microcrystalline throughout its entire structure. The thorough microcrystalline structure of the product of the present invention is provided by using microcrystalline xylitol also in the solid portion of the feed.

It is quite evident from the comparison of the DuRoss disclosure and the teachings of the present invention that the melt crystallized microcrystals of DuRoss are, as products, different from the present suspension crystallized microcrystalline products.

Based on the above arguments, it is respectfully submitted that the subject matter of claims 23-30, 35-39 and 46-56 are patentably distinct from the teachings of Dogliotti, Darsow and DuRoss and it is respectfully requested that the rejection of these claims under 35 U.S.C. §102(b) be withdrawn.

Finally, the Office Action has rejected claims 1-22 under 35 U.S.C. §102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over DuRoss. Applicants respectfully disagree with this allegation.

Again, the crystallization process according to DuRoss is a melt crystallization wherein a xylitol solution is cooked at a high temperature to provide a melt containing less than 2% moisture. The hot mixture is continuously stirred with an agitator. Just before crystallization, seed crystals of finely ground xylitol are added to the vortex of the viscous mixture and the stirring is continued at high speed. Crystallization takes place in the viscous melt. The melt mass is poured on a tray where it finally crystallizes into a white solid.

In contrast to the above, the present process comprises a suspension crystallization, wherein the xylitol crystallizes well below its melting temperature from an aqueous solution. This provides a very homogeneous crystalline product. Each crystal is separately formed in the suspending gas where it collides with and adheres to the next crystal also in the gas. The particles grow gradually into bigger, loosely adhered agglomerates.

In the melt crystallization of DuRoss, the xylitol melt forms a continuous mass, wherein the crystals crystallize within the mass, in contact with the mass and totally surrounded by the mass. The agitation breaks up crystal bridges formed in the mass and prevents the formation of one huge compact crystal cake. However, it is very evident that the discrete crystal nature of the product which is obtained in the suspension crystallization of the present invention cannot be obtained by the melt crystallization as taught by DuRoss.

Due to the discrete crystal agglomeration found in the process of the present invention, the suspension crystallized xylitol will easily break into discrete small particles which provide a freely flowing product which is very useful in industrial processes. This is not the case with DuRoss.

Moreover, it should be noted that the melt crystallization of DuRoss starts from seed crystals which are not microcrystalline in themselves. Thus, at least some of the microcrystals of DuRoss will have cores which are not microcrystalline in nature. The present invention requires that the product be crystalline throughout its entire structure. This thorough microcrystalline structure of the present invention is guaranteed by using microcrystalline xylitol in the solid portion of the feed in the process of the present invention.

Based on the above arguments distinguishing the different crystallization processes of the present invention and that of DuRoss, it is respectfully requested that the rejection of the process claims based on DuRoss be withdrawn as well.

Based on the amendments and the remarks submitted above, it is respectfully submitted that all the claims in the subject application contain patentable subject matter and a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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<u>Version With Markings to Show Changes Made</u>

<u>In the claims</u>:

<u>Claims 2, 3, 7, 8, 10, 11, 16, 19, 24 and 26-28 have been amended as follows</u>:

2. (Amended) The process according to claim 1, wherein said liquid is an aqueous solution of xylitol having a xylitol concentration of about 30-80% by weight [,preferably about 50-77% by weight].

3. (Twice amended) The process according to claim 1, comprising heating said liquid to a temperature of about 45-80° C [,preferably about 55-70°C] prior to said contacting.

7. (Twice amended) The process according to claim 1, wherein said removal of said solvent is performed by the introduction of a drying gas [such as air] heated to a temperature of about 55-170°C [, preferably about 80-150°C, most preferably about 90-130°C].

8. (Amended) The process according to claim 7, wherein said solvent removal provides a xylitol material dried to a free moisture content of about 0.1 to 3% [, preferably below 1%] while said xylitol material is still in a suspended state.

10. (Twice amended) The process according to claim 1, wherein said xylitol composition is allowed to settle on a moving belt and to form thereon a substantially continuous agglomerated porous powder layer having a thickness of about 0.5 – 5 cm [, preferably about 1-3 cm].

11. (Amended) The process according to claim 10, wherein said conditioning includes treating said composition in said agglomerated layer with a drying gas having a temperature of about 50-100°C, for a time of about 10-180 minutes [or more].

16. (Amended) The process according to claim 15, comprising recovering microcrystalline xylitol particles having a mean particle size of about 0.1 – 10 mm [, preferably about 0.15 – 0.4 mm].

19. (Twice amended) The process according to claim 1, comprising recirculating microcrystalline xylitol particles having a mean particle size below about 0.2 mm [, preferably below about 0.1 mm].

24. (Amended) The xylitol product according to claim 23, having a xylitol purity of more than 80% [, preferably more than 90%, most preferably up to 98% or more].

26. (Twice amended) The xylitol product according to claim 23, wherein about 10-90% [, preferably about 30-70%, most preferably 50-80%] of the dry substance of the final product derives from a feed of solid microcrystalline particles.

27. (Twice amended) The xylitol product according to claim 23, comprising particles having a mean particle size of about 0.1 – 2 mm [, preferably about 0.15 – 0.4 mm].

28. (Twice amended) The xylitol product according to claim 23, wherein the size of the microcrystals in each particle is on an average below 50μ [, preferably about 10μ].